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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,246	02/27/2004	Jeffrey David Bettencourt	03-862-B	9463

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EXAMINER
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CORDERO GARCIA, MARCELA M

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,246	<b>Applicant(s)</b> BETTENCOURT ET AL.	
	<b>Examiner</b> Marcela M. Cordero Garcia	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 10, 11 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10, 11 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to the reply received on April 10, 2006.

Claims 1-5, 10-11 and 17 are pending in the application.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Claims 1-5, 10-11 and 17 are presented for examination on the merits.

In the previous Office Action, dated January 10, 2006, Examiner indicated that claim 17 and claims 1-5 and 10-11 amended to include all the limitations of claim 17 were allowable, however, upon further consideration, the instantly claimed subject matter is not deemed allowable in view of the new ground of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 10-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sporeno et al. (Cytokine, 1994) in view of Newton et al. (Molecular Biotechnology, January 2002).

Sporeno et al. teach a method for purifying a 6x histidine tagged cytokine with a four-helix bundle motif with a single-step metal chelating column [i.e., a tag-specific affinity support column] from a protein preparation (e.g. abstract, lines 1-10; page 261, column 1, lines 6-10).

Sporeno et al. do not teach the use of a heparin column before the metal chelating column.

Newton et al. teaches a method for purifying a polyhistidine-tagged protein (e.g., page 65, section 3.1.d, and pages 67-69, sections 3.4 to 3.8) from a protein preparation (page 65, section 3.7), comprising:

(a) concentrating the tagged protein preparation with a negatively charged capture support, wherein the negatively charged capture support comprises heparin (page 68, section 3.8.1), comprising the steps of:

- (i) contacting the protein preparation with the capture support (page 68, section 3.8.1);
- (ii) washing the capture support with a capture support washing buffer of low ionic strength to remove interfering molecules

but not the tagged protein from the capture support. (page 68, section 3.8.2); and

- (iii) eluting the tagged protein from the capture support with a capture support eluting buffer of high ionic strength; (page 68, section 3.8.3);

(b) purifying the tagged protein from the eluate of step (a) (iii) with a tag-specific affinity support, wherein the tag-specific affinity support comprises nickel nitrilotriacetic acid, comprising the steps of:

- (i) contacting the eluate of step (a) (iii) with the tag-specific affinity support (page 68, section 3.8.1.2);
- (ii) washing the affinity support with affinity support washing buffer of low ionic strength to remove some impurities but not the tagged protein from the affinity support (page 69, section 3.8.1.4); and
- (iii) eluting the tagged protein from the affinity support with an affinity support eluting buffer (page 69, section 3.8.1.5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the metal chelating column method of Sporeno et al. by applying the 2-step metal chelating column separation of Newton et al. The skilled artisan would have been motivated to do so because Newton et al. teach that a 2-step process using a heparin column before the metal chelating column eliminates the majority of contaminating proteins during purification of polyhistidine proteins (see Newton et al., e.g., abstract and page 73, section 44).

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There would have been a reasonable expectation of success, given that both proteins were obtained from bacterial cells, were tagged with histidine and could be purified via metal chelating columns (i.e., tag-specific affinity support columns). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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MMCG 06/06



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